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10/631,116	07/31/2003	Houdin Dehnad	50623.249	7743

7590 11/01/2007  
Cameron Kerrigan  
Squire, Sanders & Dempsey L.L.P.  
Suite 300  
One Maritime Plaza  
San Francisco, CA 94111

EXAMINER
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ANDERSON, JAMES D

ART UNIT	PAPER NUMBER
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1614

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11/01/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/631,116	Applicant(s) DEHNAD, HOUDIN	
	Examiner James D. Anderson	Art Unit 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 and 43-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**CLAIMS 1-48 ARE PRESENTED FOR EXAMINATION**

Applicants' amendment filed 7/19/2007 has been received and entered into the application. Accordingly, claims 27, 33, and 35 have been amended. Claims 1-26 and 43-48 remain withdrawn from consideration per the Response to Election/Restriction filed 9/15/2006. Accordingly, claims 27-42 are presently under examination and are the subject of this Office Action.

Applicants' arguments, filed 7/19/2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***Response to Arguments***

Applicant's arguments filed 7/19/2007 have been fully considered but they are not persuasive. Claims 27-42 have been rejected as being obvious over Ding *et al.* (U.S. 5,837,313) in view of Flanagan (U.S. 6,764,709) (claims 27-33 and 35-37), or WO 03/022323 (claims 34 and 42), or EP 0970711 (claim 38), or Yang (U.S. 6,120,847) (claims 39-41).

As an initial matter, Applicant argues that WO 03/022323 is excepted as prior art under 35 U.S.C. 103 via 102(e) because the reference is commonly owned by and subject to assignment to Advanced Cardiovascular Systems, Inc. However, WO 03/022323 was published on March 20, 2003 and thus qualifies as prior art under 35 U.S.C. 102(a). The instant application was filed on July 31, 2003. As such, WO 03/022323 is available as a reference under 35 U.S.C.

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102(a) because it is “by another” (Stephen D. Pacetti) and published prior to Applicant’s invention. As such, common ownership cannot be used to overcome a 35 U.S.C. 102(a) reference.

With respect to the Flanagan reference, this reference was inadvertently added to the rejection statement. As Applicant correctly stated, the Examiner did not discuss the relevance of Flanagan. This is because Flanagan was not intended to be included in the rejection over Ding *et al.* The Examiner would like to thank the Applicant for bringing this oversight to his attention. Flanagan has been removed from the rejection that is reiterated below.

Applicant argues that Ding *et al.* do not use a “beam” of argon plasma for sterilizing the coated stent described therein and thus does not teach all of the limitations of the instant claims. Further, Applicant argues that the method of sterilization in Ding *et al.*, which is well known in the art, will not result in the claimed increased release rate of the active agent from the coating. However, there is no evidence of record that the argon plasma and electron beam treatment described in Ding *et al.* will not result in an increased release rate of active agent from the coating compared to devices that are not treated with argon plasma and electron beam. As such, and because the Office does not have laboratory equipment suitable for carrying out experiments to determine whether a prior art reference includes the functions that are now recited, the Examiner takes the position that the act of treating an coated implantable medical device with argon plasma and electron beam will result in an increased rate of drug release from the coating. This position is supported by the fact that, in addition to the argon plasma treatment (which is reasonably “charged particles” as instantly claimed), Ding *et al.* also suggests sterilization using gamma radiation, electron beam, ethylene oxide or steam sterilization. An electron beam is also

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reasonably a “beam of charged particles” as instantly claimed. Thus, the act of treating a coated stent as disclosed in Ding *et al.* with argon plasma and electron beam irradiation will naturally result in the claimed effect due to the alterations, however minor, that occur to the coating upon such treatment.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to “prove that subject matter to be shown in the prior art does not possess the characteristic relied on” (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003). In the instant case, Ding *et al.* disclose the same method steps as those instantly claimed: 1) applying polymer, active agent, and solvent to an implantable medical device; 2) allowing the solvent to evaporate to form a dry coating; and 3) “directing” charged particles (argon plasma and electron beam) to the dry coating. As such, the claimed result of such method steps, namely an increased rate of release of active agent from the coating, will naturally result from the method steps taught in Ding *et al.*

With respect to the claimed current density, the “about” modifier has not been defined in the specification. As such, “...about 0.001  $\mu\text{A}/\text{cm}^2$  to about 1  $\mu\text{A}/\text{cm}^2$ ...” reasonably reads on any current density being applied.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 27-33 and 35-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ding *et al.* (U.S. Patent No. 5,837,313; prior art of record).

The instant claims are drawn to a method of manufacturing a drug eluting implantable medical device, comprising applying a composition comprising a polymer, an active agent and a solvent, allowing the solvent to evaporate and subsequently directing a beam of charged particles to the dry polymeric coating.

Ding *et al.* disclose a method of coating an implantable open lattice metallic stent comprising sequentially applying a plurality of relatively thin outer layers of a coating composition comprising a solvent mixture of uncured polymeric silicone material and crosslinker and finely divided biologically active species. Agents suitable for incorporation include antithrobotics, anticoagulants, antiplatelet agents, thrombolytics, antiproliferatives, antiinflammatories and agents that inhibit hyperplasia and in particular restinosis (col. 4, lines 63-66). This teaching reasonably suggests and motivates the instantly claimed derivatives of rapamycin (which are known antiproliferatives and prevent restinosis). The coatings are cured and subjected to argon gas plasma and exposure to gamma radiation, electron beam, ethylene oxide or steam sterilization (Abstract; col. 4, lines 21-25). In the plasma treatment, coated stents are placed in a reactor chamber and inert gas (*e.g.*, argon) is admitted to the reactor chamber at varying power ranges and flow rates (*id.* at lines 26-39). This teaching reasonably correlates with a “directed” beam as such a limitation does not suggest that said beam must be narrow. As

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such, introducing argon plasma through a flow port meets the claimed limitation of “directing a beam of charged particles”. Further, applying an “electron beam” to the coated stents as disclosed in Ding *et al.* reasonably teaches the claimed “directing a beam of charged particles”. Polymers suitable for the coatings taught in the reference include polyurethanes as instantly claimed (col. 4, lines 48-62). The solvent is evaporated in the curing process, often at elevated temperatures (col. 8, lines 21-37). It flows from the disclosure of Ding *et al.* that such evaporation will result in the residual solvent percentages instantly claimed. With respect to instant claims 33 and 35-36, which recite forming a barrier layer of polymer comprising no active agent, the reference teaches that multiple layers may be employed wherein one or may layers do not contain active agent (col. 10, lines 50-59).

In the absence of a showing demonstrating the criticality of the instantly claimed current density, no unobviousness is seen in adjusting the flow rate and power of the argon plasma treatment or electron beam in order to reach the claimed current density. Further, as discussed *supra*, the “about” modifier has not been defined in the specification. As such, “...about 0.001  $\mu\text{A}/\text{cm}^2$  to about 1  $\mu\text{A}/\text{cm}^2$ ...” reasonably reads on any current density being applied.

Claims 34 and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ding *et al.* (U.S. Patent No. 5,837,313; prior art of record) as applied to claims 27-33 and 35-37 above, and further in view of WO 03/022323 (Published March 20, 2003) (prior art of record).

Ding *et al.* discloses as discussed *supra*. The reference does not disclose use of a polymer with a percent crystallinity of about 50% as recited in instant claim 34 or exposing the

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dry coating to a temperature equal to or greater than the glass transition temperature of the polymer in the coating as recited in instant claim 42.

However, WO 03/022323 discloses coatings for reducing the rate of release of drugs from stents and is thus drawn to the same subject matter disclosed in Ding *et al.* WO '323 discloses the use of polymers with crystallinity of not less than 10%, preferably not less than 50% (page 6, ¶ [0017]). This reasonably suggests the limitations of instant claim 34. Further, WO '323 discloses that when thermoplastic polymers are used (such as the instantly claimed polymers), the deposited primers should be exposed to heat at a temperature greater than the glass transition temperature of the selected polymer (page 15, ¶ [0017]) thus teaching the limitation of instant claim 42.

In the absence of a showing of unexpected results commensurate in scope with the claims, the instantly claimed methods would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. WO '323 explicitly motivates the skilled artisan to use polymers with crystallinity of not less than 10%, preferably not less than 50% and exposing polymers to heat at a temperature greater than the glass transition temperature of the selected polymer. The motivation to combine the references is reasonably suggested wherein all of the references are drawn to medical devices identically coated with polymers and active agents.

Claim 38 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ding *et al.* (U.S. Patent No. 5,837,313; prior art of record) as applied to claims 27-33 and 35-37 above, and further in view of EP 0970711.

Ding *et al.* discloses as discussed *supra*. The reference does not disclose masking a portion of the coating by inserting a mandrel prior to directing a beam of charged particles as required by the limitations of claim 38.

However, EP '711 discloses a method of controlling the thickness of a polymer coating applied to the inner surface of a stent by fitting a mandrel within its interior (§ [0006]). This mandrel is disclosed to minimize or eliminate polymer coating on the inner surface of the stent. EP '711 also discloses the same polymeric coating instantly claimed (§ [0023] to [0025]) as well as a polymeric coating comprising the therapeutic agent rapamycin (§ [0030] and Example 7).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the mandrels disclosed in EP '711 to protect the inner surface of an implantable medical device (*e.g.* a stent) from the argon plasma disclosed in Ding *et al.* One skilled in the art would be motivated to do so because EP '711 discloses that it is often desirable for the inner and outer surfaces of implantable stents to have different properties, including drug elution profiles. Further, the skilled artisan would have been imbued with at least a reasonable expectation that exposure of the outer polymer to a beam of charged particles while protecting the inner polymer, would result in different chemical and structural properties of the respective polymers. The motivation to combine the references is reasonably suggested wherein all of the references are drawn to medical devices identically coated with polymers and active agents.

Claims 39-41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ding *et al.* (U.S. Patent No. 5,837,313; prior art of record) as applied to claims 27-33 and 35-37 above, and further in view of Yang *et al.* (U.S. Patent No. 6,120,847).

Ding *et al.* discloses as discussed *supra*. The reference does not disclose exposing the dry coating to a fluid to remove polymer fragments from the coating as required by the limitations of claims 39-41.

However, Yang *et al.* disclose a surface treating method for stent coating that eliminates surface imperfections on a medical device having a drug release coating including a therapeutic substance in a polymeric carrier disposed on at least a portion of the medical device (Abstract). The polymers used in the coatings include the instantly claimed poly(L-lactide) (col. 3, lines 31-44). The applied coating comprises a solvent, a polymer, and a therapeutic agent and the solvent is evaporated to leave on the stent surface a coating of the polymer and the therapeutic agent (col. 4, lines 1-2 and 24-27). Because the procedures for applying the polymeric surface treatments leave polymeric fibers, polymeric particles or other polymeric surface aberrations, there is a need to eliminate or reduce the unwanted imperfections. As such, Yang *et al.* disclose a method of contacting a coated stent having polymeric imperfections with a vaporized solvent (col. 5, lines 18-35). Organic solvents can be used and the reference states that not only the vapor, but also the fluid itself can be used to remove polymer imperfections (col. 5, lines 36-44 and 57-60). This teaching reasonably suggests that any solvent with the same properties (*e.g.* capability to remove surface imperfections) could also be used.

In the absence of a showing of unexpected results commensurate in scope with the claims, the instantly claimed methods would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Yang *et al.* provide the motivation to contact a coated stent with a solvent wherein it is disclosed that such contact can remove polymeric imperfections from the coated stent. The motivation to combine the references is reasonably

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suggested wherein all of the references are drawn to medical devices identically coated with polymers and active agents.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

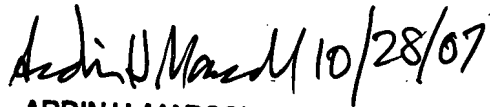
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
James D. Anderson  
Patent Examiner  
AU 1614

October 26, 2007

  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER